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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/552,485	04/18/2000	Claude Singer	1662/49502	2266

26646 7590 08/26/2002

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EXAMINER

HABTE, KAHSAY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/26/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/552,485

Applicant(s)

SINGER ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-35,37-41 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-35,37-41 and 46-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 19.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 30-35, 37-41, and 46-53 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/13/02 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-35 and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 30 and 37, the term "crystalline" lacks descriptive support. There is only support for the phrase "adduct of mirtazapine" in the specification. Applicants can use original claim 24 for

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descriptive support. This can be done by putting the subject matter of claim 24 into the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims ⁶30-35 and ⁵37-41 are rejected under 35 U.S.C. 102(b) as being unpatentable over Kaspersen *et al.* Kaspersen *et al.* on page 1066 teaches crystallization of mirtazapine crude product from methanol/water to achieve colorless crystals. In claims 30-35 and 37-41, there has been recited a crystalline adduct or an adduct of mirtazapine and the method of its preparation (precipitation from organic solvents such as alcohols). It appears to be the same process and therefore the products are presumed to be the same, i.e. inherently formed. See *In re Zelinski* 141 USPQ 217, *In re Best* 195 USPQ 432, and *In re Wiegand* 86 USPQ 155.

5. Claims 46-53 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kaspersen *et al.* {Journal of Label. comp. and Radiopharm., 27, No. 9, 1055 (1989)}. Kaspersen *et al.* teaches the multi-step synthesis of Org-3770 (mirtazapine) on page 1058 (Fig.4). On page 1066, Kaspersen *et al.* teaches the synthesis of mirtazapine and

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the crystallization of the mirtazapine (compound **1c**) from the crude product using methanol/water solvent mixture to achieve almost pure crystals. Compound **1c** is ¹³carbon labeled product, but since the claim embraces the labeled compounds, the crystals product acquired from this process are identical to the claimed crystals of mirtazapine. The synthesis of compound **1d** on page 1067 also can be used as an additional prior art, even though Kaspersen et al. did not provide any information on the specific nature of the product (solid, crystal, or oily). Since compound **1c** and **1d** are the same compounds, therefore compound **1d** is also presumed to be crystal. These products (crystals from compound **1c**) including compound **1d**, are exactly the same compounds (crystals of mirtazapine) claimed by the applicants.

Declaration under 37 C.F.R. §1.132

6. The declarations by Judith Aronhime and by Claude Singer are acknowledged but they were not persuasive enough to overcome the rejection for the following reasons:

a. The declaration by Aronhime and Singer did not establish that Kaspersen's product falls beyond the claim. It was only established that applicant's product (adduct of mirtazapine) contains 0.2 to 3.2% by weight water. Aronhime and Singer did not establish whether or not Kaspersen's product is free of water or contains more than about 3% water by weight. Thus, it is unknown whether it is more than about 3% or less than 0.2%. The declaration did not establish that the claims do not embrace the Kaspersen product without actually making the Kaspersen product.

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b. In the declaration (Aronhime), it is not clear where the IR peak at 1467 cm^{-1} came from. Before drying the IR peak was 1444 cm^{-1} , and drying simply cannot generate a fresh IR peak. An explanation is needed.


Applicants also can overcome the rejection for claims which have crystalline, if they show that Kaspersen product cannot form a crystalline material. But note that Kaspersen specifically say that his material is crystalline.

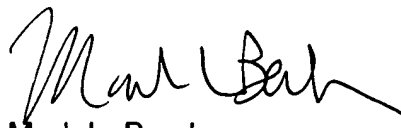
Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624


Mark L. Berch
Primary Examiner
Art Unit 1624

KH
August 22, 2002